

|  |   |    |                          |                        |            |
|--|---|----|--------------------------|------------------------|------------|
| Substitute for form 1449/PTO   |   |    | <b>Complete if Known</b> |                        |            |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br><i>(Use as many sheets as necessary)</i> |   |    | Application Number       | 10/693233              |            |
|  |   |    | Filing Date              | October 24, 2003       |            |
|  |   |    | First Named Inventor     | KAYMAKALAN, Zehra      |            |
|  |   |    | Art Unit                 | 1644                   |            |
|  |   |    | Examiner Name            | SKELDING, ZACHARY S.   |            |
| Sheet  | 1 | of | 3                        | Attorney Docket Number | BBJ-190RCE |

| U.S. PATENT DOCUMENTS |              |   |                                |  |   |
|-----------------------|--------------|---|--------------------------------|--|---|
| Examiner<br>Initials* | Cite<br>No.* | Document Number<br>Number-Kind Code* (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|                       | A1           | US5998378                                       | 12-07-1999                     | Kriegler   |   |
|                       | A2           | US6267958                                       | 7-31-2001                      | Andya et al.                                       |   |
|                       | A3           | US5237054                                       | 08-17-1993                     | Brinks et al.                                      |   |
|                       | A4           | US4897465                                       | 01-30-1990                     | Cordle et al.                                      |   |
|                       | A5           | US7141542                                       | 11-28-2006                     | Cowan et al.                                       |   |
|                       | A6           | US5608038                                       | 04-03-1997                     | Eibi et al.  |   |
|                       | A7           | US6165467                                       | 12-26-2000                     | Hagiwara et al.                                    |   |
|                       | A8           | US6485725                                       | 11-26-2006                     | Hirao et al.                                       |   |
|                       | A9           | US7220409                                       | 05-22-200                      | Norman et al.                                      |   |
|                       | A10          | US7318931                                       | 01-15-2008                     | Okumu et al.                                       |   |
|                       | A11          | US6737405                                       | 05-18-2004                     | Roemisch et al.                                    |   |
|                       | A12          | US6818613                                       | 11-16-2004                     | Sharma et al.                                      |   |
|                       | A13          | US5654403                                       | 08-05-1997                     | Smith et al.                                       |   |
|                       | A14          | US5792838                                       | 08-11-1998                     | Smith et al.                                       |   |
|                       | A15          | US4597966                                       | 07-01-1986                     | Zolton et al.                                      |   |
|                       | A16          | US2006/0127395                                  | 06-15-2006                     | Arvinte et al.                                     |   |
|                       | A17          | US2007/0243185                                  | 10-18-2007                     | Gombotz et al.                                     |   |
|                       | A18          | US2004/0156835                                  | 08-12-2004                     | Imoto et al.                                       |   |
|                       | A19          | US2003/0138417                                  | 07-24-2003                     | Kaisheva et al.                                    |   |
|                       | A20          | US2003/0190316                                  | 10-09-2003                     | Kakuta et al.                                      |   |
|                       | A21          | US2005/0214278                                  | 09-29-2005                     | Kakuta et al.                                      |   |
|                       | A22          | US2005/0118163                                  | 06-02-2005                     | Mizushima et al.                                   |   |
|                       | A23          | US2005/0118167                                  | 06-02-2005                     | Okada et al.                                       |   |
|                       | A24          | US2004/0038878                                  | 02-26-2004                     | Tanikawa et al.                                    |   |
|                       | A25          | US2004/0213785                                  | 10-28-2004                     | Yamazaki et al.                                    |   |
|                       | A26          | US2006/0182740                                  | 08-17-2006                     | Yang et al.  |   |
|                       | A27          | US7223394                                       | 05-29-2007                     | Salfeld et al.                                     |   |
|                       | A28          | US7541031                                       | 06-02-2009                     | Salfeld et al.                                     |   |
|                       | A29          | US7588761                                       | 09-15-2009                     | Salfeld et al.                                     |   |
|                       | A30          | US2010/0016557 A1                               | 01-21-2010                     | Salfeld et al.                                     |   |
|                       | A31          | US2009/0155205 A1                               | 06-18-2009                     | Salfeld et al.                                     |   |
|                       | A32          | US2003/0235585 A1                               | 12-25-2003                     | Fischkoff et al.                                   |   |
|                       | A33          | US2004/0033228 A1                               | 02-19-2004                     | Krause et al.                                      |   |
|                       | A34          | US2006/0153846 A1                               | 07-13-2006                     | Krause et al.                                      |   |
|                       | A35          | US2003/0206898 A1                               | 11-06-2003                     | Fischkoff et al.                                   |   |
|                       | A36          | US2004/0009172 A1                               | 01-15-2004                     | Fischkoff et al.                                   |   |
|                       | A37          | US2004/0166111 A1                               | 08-26-2004                     | Kaymakalan et al.                                  |   |
|                       | A38          | US2006/0009385 A1                               | 01-12-2006                     | Hoffman et al.                                     |   |
|                       | A39          | US2009/0304682 A1                               | 12-10-2009                     | Hoffman et al.                                     |   |
|                       | A40          | US2006/0083741 A1                               | 04-20-2006                     | Hoffman et al.                                     |   |
|                       | A41          | US2007/0041905 A1                               | 02-22-2007                     | Hoffman et al.                                     |   |
|                       | A42          | US2007/0081996 A1                               | 04-12-2007                     | Hoffman et al.                                     |   |
|                       | A43          | US2007/0071747 A1                               | 03-29-2007                     | Hoffman et al.                                     |   |
|                       | A44          | US2007/0172897 A1                               | 07-26-2007                     | Maksymowych et al.                                 |   |
|                       | A45          | US2007/0292442 A1                               | 12-20-2007                     | Wan et al.   |   |
|                       | A46          | US2009/0110679 A1                               | 04-30-2009                     | Li et al.  |   |

|   |   |    |                          |                        |            |
|---|---|----|--------------------------|------------------------|------------|
| Substitute for form 1449/PTO  |   |    | <b>Complete if Known</b> |                        |            |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |   |    | Application Number       | 10/693233              |            |
|   |   |    | Filing Date              | October 24, 2003       |            |
|   |   |    | First Named Inventor     | KAYMAKALAN, Zehra      |            |
|   |   |    | Art Unit                 | 1644                   |            |
|   |   |    | Examiner Name            | SKELDING, ZACHARY S.   |            |
| Sheet   | 2 | of | 3                        | Attorney Docket Number | BBI-190RCE |

|     |                   |            |                    |
|-----|-------------------|------------|--------------------|
| A47 | US2009/0291062 A1 | 11-26-2009 | Fraunhofer et al.  |
| A48 | US2008/0166348 A1 | 07-10-2008 | Kupper et al.      |
| A49 | US2009/0028794 A1 | 01-29-2009 | Medich et al.      |
| A50 | US2009/0317399 A1 | 12-24-2009 | Pollack et al.     |
| A51 | US2008/0118496 A1 | 05-22-2008 | Medich et al.      |
| A52 | US2009/0123378 A1 | 05-14-2009 | Wong et al.        |
| A53 | US2008/0131374 A1 | 06-05-2008 | Medich et al.      |
| A54 | US2008/0311043 A1 | 12-18-2008 | Hoffman et al.     |
| A55 | US2010/0021451 A1 | 01-28-2010 | Wong et al.        |
| A56 | US2009/0017472 A1 | 01-15-2009 | Stuhlmüller et al. |
| A57 | US2009/0258018 A1 | 10-15-2009 | Medich et al.      |
| A58 | US2008/0227136 A1 | 09-18-2008 | Pia et al.         |
| A59 | US2009/0239259 A1 | 09-24-2009 | Hsieh et al.       |
| A60 | US2009/0226530 A1 | 09-10-2009 | Lassner et al.     |
| A61 | US2009/0271164 A1 | 10-29-2009 | Peng et al.        |
| A62 | US2010/0003243 A1 | 01-07-2010 | Okun et al.        |
| A63 | US2004/0126372 A1 | 07-01-2004 | Banerjee et al.    |
| A64 | US2007/0202104 A1 | 08-30-2007 | Banerjee et al.    |
| A65 | US2004/0131614 A1 | 07-08-2004 | Banerjee et al.    |
| A66 | US2004/0126373 A1 | 07-01-2004 | Banerjee et al.    |
| A67 | US2004/0151722 A1 | 08-05-2004 | Banerjee et al.    |
| A68 | US2004/0136991 A1 | 07-08-2004 | Banerjee et al.    |
| A69 | US2008/0193466 A1 | 08-14-2008 | Banerjee et al.    |
| A70 | US2004/0136990 A1 | 07-15-2004 | Banerjee et al.    |
| A71 | US2004/0219142 A1 | 11-04-2004 | Banerjee et al.    |
| A72 | US2004/0136989 A1 | 07-15-2004 | Banerjee et al.    |
| A73 | US2003/0012786 A1 | 01-16-2003 | Tech et al.        |
| A74 | US2003/0161828 A1 | 08-28-2003 | Abdelghany et al.  |

| FOREIGN PATENT DOCUMENTS |          |  |                                |   |  |
|--------------------------|----------|--|--------------------------------|---|--|
| Examiner Initials*       | Cite No. | Foreign Patent Document<br>Country Code <sup>1</sup> -Number <sup>2</sup> -Kind Code <sup>3</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear<br>† |
|                          | B1       | EP 0486526 A1  | 05-27-1992                     | Peptide technol. Ltd.                           |  |
|                          | B2       | WO 01/94585  | 12-13-2001                     | Celltech R&D Ltd.                               |  |
|                          | B3       | EP0929578  | 5-2-2003                       | BASF AG   |  |
|                          | B4       | WO 01/60420  | 08-23-2001                     | Aeropharm Technology, Inc                       |  |
|                          | B5       | WO 02/072636   | 09-19-2002                     | Altus Biologics, Inc.                           |  |
|                          | B6       | WO 99/37329  | 07-29-1999                     | Astra Aktiebolag                                |  |
|                          | B7       | WO 90/01191  | 02-08-1990                     | BMC Software, Inc.                              |  |
|                          | B8       | WO 98/44948  | 10-15-1998                     | Cangene Corporation                             |  |
|                          | B9       | EP 417191  | 10-03-1993                     | Centcor, Inc.                                   |  |
|                          | B10      | WO 00/67798  | 11-16-2000                     | CSL Limited                                     |  |
|                          | B11      | WO 03/066681   | 08-14-2003                     | Delta Biotechnology Ltd.                        |  |
|                          | B12      | WO 97/45140  | 12-04-1997                     | Glaxo Group Ltd.                                |  |
|                          | B13      | WO 02/64166  | 08-22-2002                     | Korea Inst. for Science                         |  |
|                          | B14      | WO 04/007520   | 01-22-2004                     | Medarex, Inc.                                   |  |
|                          | B15      | EP 419251  | 01-09-1993                     | Mitsui Toatsu Chemicals                         |  |

|   |   |                          |                      |
|---|---|--------------------------|----------------------|
| Substitute for form 1449/PTO  |   | <b>Complete if Known</b> |                      |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |   | Application Number       | 10/693233            |
|   |   | Filing Date              | October 24, 2003     |
|   |   | First Named Inventor     | KAYMAKALAN, Zehra    |
|   |   | Art Unit                 | 1644                 |
|   |   | Examiner Name            | SKELDING, ZACHARY S. |
| Sheet   | 3 | of                       | 3                    |
|   |   | Attorney Docket Number   | BB1-190RCE           |

|     |              |            |                           |  |
|-----|--------------|------------|---------------------------|--|
| B16 | WO 95/03826  | 02-09-1995 | Pasteur Merieux Serums    |  |
| B17 | WO 03/009817 | 02-06-2003 | Protein Design Labs, Inc. |  |
| B18 | WO 96/07429  | 03-14-1996 | Red Cross Foundation      |  |
| B19 | WO 93/08837  | 05-13-1993 | The Wellcome Foundation   |  |
| B20 | WO 00/50079  | 08-31-2000 | Tobinick E.L.             |  |
| B21 | WO 02/80891  | 10-17-2002 | A+ Science Invest AB      |  |

\*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* Applicant's unique citation designation number (optional). \* See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. \* Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \* For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \* Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. \* Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS |                       |   |  |                |
|---------------------------------|-----------------------|---|--|----------------|
| Examiner Initials               | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.   |  | T <sup>2</sup> |
|                                 | C1                    | RAU et al, Experiences with D2E7, Aktuelle Rheumatologie 25(3): 83-88, 2000. [English Translation]  |  |                |
|                                 | C2                    | KEFFER et al., Transgenic mice expressing human tumour necrosis factor: a predictive genetic model of arthritis. EMBO J. 10(13): 4025-4031, 1991.   |  |                |
|                                 | C3                    | TAYLOR et al., Anti-tumor necrosis factor therapies. Curr. Opin. Rheumatol. 13(3): 164-169, 2001.   |  |                |
|                                 | C4                    | ZHOU et al., [New drugs for treating Rheumatoid Arthritis] (Chinese). China Pharmacist 2(2): 109, 1999.   |  |                |
|                                 | C5                    | LORENZ et al., Perspectives for TNFalpha-targeting therapies. Arthritis Research 4(Suppl 3): S17-S24, 2002.   |  |                |
|                                 | C6                    | LORENZ, "Biological Agents: a novel approach to the therapy of rheumatoid arthritis", Expert opinion on investigational drugs, Ashley Publications Ltd. London, GB Vol. 9, No 7, 2000, pages 1479-1490, ISSN: 1354-3784.  |  |                |
|                                 | C7                    | LOVELL et al., Long-term efficacy and safety of etanercept in children with polyarticular-course juvenile rheumatoid arthritis: interim results from an ongoing multicenter, open-label, extended-treatment trial. Arthritis and Rheumatism 48(1): 218-226, 2003. |  |                |
|                                 | C8                    | PENNINGTON et al., Polyclonal and monoclonal antibody therapy for experimental Pseudomonas aeruginosa pneumonia. Infect. Immun. 54: 239-244, 1986.  |  |                |
|                                 | C9                    | SHIMOZATO et al., Suppression of tumor necrosis factor alpha production by a human immunoglobulin preparation for intravenous use. Infect. Immun. 58: 1384-1390, 1990.  |  |                |
|                                 | C10                   | SIVASAI et al., Cytomegalovirus immune globulin intravenous (human) administration. Clin. Exp. Immunol. 119: 559-565, 2000.   |  |                |
|                                 | C11                   | Medline Plus Arthritis Actualizado 02-02-2002   |  |                |

Not in english and no english language abstract provided

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

|                    |                    |                 |            |
|--------------------|--------------------|-----------------|------------|
| Examiner Signature | /Zachary Skelding/ | Date Considered | 08/01/2010 |
|--------------------|--------------------|-----------------|------------|